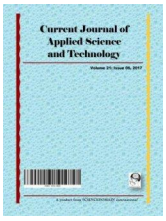

Current Journal of Applied Science and Technology

29(5): 1-8, 2018; Article no.CJAST.43874
ISSN: 2457-1024
(Past name: British Journal of Applied Science & Technology, Past ISSN: 2231-0843, NLM ID: 101664541)

Quality Management of the Pre-Analytical Phase of Total Laboratory Testing Process: Monitoring and Control

Tunji Akande[1*]

[1]Department of Chemical Pathology, Bingham University, Jos Campus, Nigeria.

Author's contribution

The sole author designed, analyzed, interpreted and prepared the manuscript.

Article Information

DOI: 10.9734/CJAST/2018/43874
Editor(s):
(1) Dr. Yahya Elshimali, Professor, Department of Internal Medicine, Charles Drew University of Medicine and Science, USA.
Reviewers:
(1) Henry Mbah, Malawi.
(2) Eric Agyeman-Duah, University of Ulm, Germany.
(3) Manickam Tamilselvi, Osmania University, India.
Complete Peer review History: http://www.sciencedomain.org/review-history/26691

Review Article

Received 02 July 2018
Accepted 10 October 2018
Published 19 October 2018

ABSTRACT

Background: Laboratory testing is a complex process comprising three phases that include the preanalytical, analytical and the post analytical phase of total laboratory testing process. Pre-analytical phase represents the most error prone phase of the laboratory testing process. Consequently, many problems arise mostly at pre-analytical phase of non-laboratory settings which are outside the control of the laboratory before the analysis of the submitted specimens.
Objectives: To evaluate the monitoring and control of errors in the non-laboratory related pre-analytical phase of the total testing process.
Methods: A literature review of the continuous quality improvement and Quality Assurance (CQI/QA) components of the preanalytical phase of total laboratory testing process.
Results: The prevalence of preanalytical errors is approximately 70% of all errors that occurred in laboratory diagnostics. Many of the variables are outside the traditional laboratory areas. Errors in the pre-analytical phase can result in misdiagnosis and mismanagement and consequently compromise patient's safety. Errors presentation at this stage requires good communication and co-operation among all health professionals involved in the total testing process from the time a laboratory request is made until the sample is ready for testing.

**Corresponding author: E-mail: tunjiakande007@yahoo.com;*

Conclusion: In non-laboratory settings, continuous monitoring and control of the initial phase of the total testing process is critical in order to reduce pre-analytical errors so that the laboratory can achieve accurate and reliable results. Non-laboratory errors in pre-analytical phase can be monitored and controls by timely and effective coordination of health care professionals for improved patient's safety and reliable testing outputs.

Keywords: Pre-analytical errors; quality management; monitoring and control.

1. INTRODUCTION

The total laboratory testing process includes three phases: the preanalytical, the analytical and the post analytical phase. From previous studies, the proportion of errors associated with the non-laboratory phases is 4-5 times that is seen in the analytical phase with the preanalytical phase consistently representing over half of all errors. Majority of diagnostic laboratory errors are either preanalytical (46–68%) or postanalytical (18-46%) while the analytical is only (7-13%). The pre-analytical phase is the most complex of the total testing process as pre-analytical errors are estimated to account for approximately 70% of all errors that occurred in laboratory diagnostics [1,2]. Studies have shown that more than 60-70% of the most important decisions on admission, discharge and medication are based on laboratory test results indicating the high degree of influence and the importance of the quality of laboratory testing and reporting [3,4]. The pre-analytical phase consists of two categories, the “pre”-pre-analytical phase and the “conventional” pre-analytical phase [5,6]. The management of quality in medical laboratories today is generally subject to national or international guidelines for good clinical laboratory practice [7]. The International Organization for Standardization (ISO) 15189:2012 standard for medical laboratories – particular requirements for quality and competence, provides a framework for the design and improvement of laboratory process-based on quality management systems [8]. Laboratory service is a highly dynamic sector of healthcare. The implementation of a quality management systems is a major issue for patient safety both inside and outside the walls of the medical laboratory [9]. Some important pre-analytical phase of laboratory process is generally held outside the medical laboratory environment, which are not under total control of laboratory management [10]. Therefore, active monitoring and control of all possible defects that are could occurred among non-laboratory personnel is essential in order to incorporate actions outside the laboratory in the laboratory quality assurance plan. This article discussed the monitoring and control of pre-analytical errors in non-laboratory settings for continuous quality improvement in laboratory testing.

1.1 Pre-analytical Errors

The pre-analytical phase of the total laboratory testing process is where the majority of laboratory errors occur [11,12]. Studies have shown that pre-analytical errors predominated in the laboratory ranging from 31.6% to 75% [13].

The pre-analytical phase can be classified into two namely the “Pre”-pre-analytical constituting (46-68%) and the “true” or “conventional” pre-analytical phase (3-5%) [14,15]. The “Pre” pre-analytical phase refers to the time between the tests ordering until samples receiving time by the laboratory [16] while the “conventional” pre-analytical step involves the process required to make sample suitable for analysis which included; centrifugation, aliquoting, diluting and sorting specimens into batches for their introduction into automated analyzers [17,18].

The commonest causes of errors in the ‘Pre’ pre-analytical phase include inappropriate test request, order entry, patient/specimen mis-identification, sample collected from infusion route, sample collection (hemolysis, clotting, insufficient volume etc), inappropriate container, handling, storage and transportation [19]. The sources of error in the ‘conventional’ pre-analytical phase includes sorting and routing, aliquoting, pipetting, centrifugation (time and/or speed) [20]. In laboratories, analytical errors are mostly all alike: every method has some amount of analytical error in the form of systematic and random error, however with pre-analytical, each laboratory has pre-analytical errors in their own way [20]. While the analytical process is essentially the same in each laboratory (the instrument and methods are designed to perform the same process), the path that the patient

specimen takes to reach the instrument is unique to each healthcare setting [21]. Accordingly, since the problems tend to be unique, the solutions must often be customised. There is no standardised list of errors upon which all laboratories and regulators agree. It is therefore important for each laboratory to perform a systems analysis of its own laboratory testing system to identify these areas where errors are likely to occur. There are seemingly unlimited ways by which a specimen can go wrong before it reaches the laboratory and the analytical system. Once the processes have been documented, the processes that are most susceptible to error should be identified and should receive the most attention [21,22].

1.2 Components of an Effective Quality Control Monitoring

The implementation and monitoring of quality indicators should be considered essential components in continuous quality improvement program. Some components of an effective pre-analytical quality control program include:

1. Correct Ordering of tests – Careful monitoring of test request and their appropriateness is likely to increase in importance and the laboratory will likely have a role in identifying situations in which test utilisation can be optimised. Delayed and lost test requisitions, specimens and reports have been major problems for the laboratories (Table 1).
2. Patient Preparation – The patient must be informed of any pretest preparations such as fasting or medical restrictions. Proper patient preparation is essential for the test results to be meaningful. Specific enquiry should be made regarding patient preparation before specimens are collected and efforts should be made to correct noncompliance. Compliance is monitored directly when the laboratory employs its own phlebotomists [23].
3. Correct Identification of the patient by the phlebotomist- The name and identification on the collection sample and the request form must match each other and must also match the correct patients [24].
4. Proper specimen collection- The specimen must be collected in the correct container and under conditions specified by the test procedure.

The techniques used to acquire a specimen affect many laboratory tests. Improper containers and incorrect preservation greatly affect test results and make them inappropriate [25].

5. Specimen Transportation – The stability of specimen during transport from the patient to the laboratory is seldom monitored, however, this aspect may be critical for some tests when performed locally and for most tests when sent to regional centers and commercial laboratories. In controlling specimen transport, the essential feature is the authority to reject specimens that arrive in the laboratory in an obviously unsatisfactorily conditions [26].
6. Specimen separation and aliquoting – Separating and aliquoting blood specimens are more directly under the control of the laboratory. The main variables are the centrifuges, the containers used and the personnel for QC purposes, centrifuges should be monitored by checking the speed timer and personnel [27,28].

Unfortunately, these procedures cannot be verified or monitored by statistical procedures, the indication that there has been a lapse in quality in this area usually reaches the laboratory in the form of a complaint or a report of a quality compromising event. The possible compromise in quality is then evaluated by a formalised process that defines the indicator of the possible lapse in quality, standards of performance for the indicator, and mechanism for and monitoring the performance. Most pre-analytical quality assurance monitoring procedures, take this problem-oriented approach to ensure quality [28].

1.3 Quality Management Systems

Quality management systems has been described as the implementation of scientific method; or the Plan-do-check-Act cycle (PCDA) [29]. The PCDA cycle is represented by components for quality laboratory processes, quality control, quality assessment, quality improvement and quality planning- all of which have centered on the quality goals, objectives and requirements to be achieved by the medical laboratory [29].

Quality management systems involves policies, processes and procedures that are needed to organise implement and support laboratory testing [30]. Quality assurance is the outcome of this quality management process. It takes well-planned and well managed activities of every step taken from the test ordering to the point of analysis of sample in the laboratory to achieve quality. Standard operating procedures (SOPs) are the starting point in managing quality. Medical laboratories must implement systematic processes that are performed in the same way by all personnel. Efforts must also be made toward increased education and training of laboratory personnel, particularly in the minute details of these critical processes. This is an area where accreditation guidelines (ISO) and standards for clinical laboratory practice (CLSI, ISO) with the practical needs of the laboratory. These institutions require well-defined and detailed procedures and manuals. It is essential that the laboratory analysts have the correct instructions, if he or she must perform laboratory procedures correctly. In addition, competent and well-trained personnel who would ensure errors free and reliable testing [30].

The most common pre-analytical errors include inappropriateness of test order, patient identification error, timing errors in sampling and preparation, hemolysis and lipemic blood samples, inappropriate transport and inadequate and inappropriate sample collection tube (Table 2).

Getting everyone to do the same thing is a requirement if quality is to be managed anywhere in the laboratory and in any phase of the testing process. All of these instructions need to be documented in a clear format well understood and made available to all staff. In addition, all laboratory staff must be trained and periodic refresher training is required for staff to be able to carry out relevant procedures correctly [31].

Quality management systems is defined as the organisation, structure, resources, processes and procedures to implement quality management. Therefore, the PDCA cycle that we have adopted provides a quality management process and its components quality planning (QP), quality laboratory procedure (QLP), quality control (QC), quality assurance (QA), quality improvement (QI) are sub-processes and procedures while there is a certain organisation and structure to this model, it does not consider the management organisation, laboratory structure, and laboratory resources that are necessary to support quality management in the laboratory [32]. Review of the accreditation criteria, patient safety concerns and discussions in the literature indicate some clear areas for action for laboratories that want to extend their quality attention outside the physical confines "outside the box" of the laboratory. The areas of highest priority in the pre-analytical phase are patient/sample identification. Laboratories can develop clear sample acceptance and rejection criteria which are linked to monitoring of the collection and transportation processes. Sample hemolysis and clotting are the commonest causes of unsuitable blood specimens and most laboratories have procedures to handle such specimen at sample receipt, but a more pro-active approach is extending this back to the point of collection [33,34]. The laboratories procedures regarding unlabeled or mislabeled specimens should be clear and sample relabeling by laboratory personnel, clinical staff or third parties is strongly discouraged [35,36]. Collection procedure, container, transport temperature/time/safety and within – laboratory pre-analytical temperature/time/ safety criteria should be stipulated and monitored.

Regular and periodic inspection of pre-analytical phase should be carried out by teams of practicing laboratory professionals using standard checklist which cover general laboratory functions as well as specific disciplines. The standard checklist questions should be explicit in their intent and the required evidence or compliance (e.g., records, written procedures and policies). More than 6,000 laboratories worldwide are college of American Pathologists (CAP) accredited [5]. The laboratory general checklist specifically refers to the monitoring of pre-analytical quality and the CAP laboratory patient safety goals which requires the quality management program to include monitoring important key indicators of quality including patient / sample identification, test order accuracy and specimen acceptability.

Table 1. Error tracking in medical laboratory testing at the pre-analytical phase

Phase	Possible errors
Ordering	Sample without order Duplicate order Incorrect test Not readable Incorrect time/date Incorrect priority Typing error
Collection	Forgotten Failed Incorrect tube Lost tube Incorrect volume Incorrect temperature Incorrect treatment Patient state not appropriate (example: patient not fasting Incorrect time/date Incorrect priority Tube missing Patient missing
Identification (this type of error can occur at any point throughout the total testing process	Insufficient clinical information Missing/incorrect patient ID Missing/incorrect physician ID Incorrect patient Incorrect labeling
Transportation	Forgotten/missing/lost Incorrect sorting Misrouted specimen (example sent to many lab) Incorrect packing Incorrect treatment during transport (example not refrigerated)
Sample preparation	Centrifugation Incorrect speed/time Too late Tube broken Label lost Incorrect temperature Insufficient centrifugation Pipetting Forgotten Too late Incorrect pipetting Freezing Forgotten Delayed freezing Incorrect temperature Sample stability exceeded Icterus Hemolysis Lipemia Delayed coagulation Coagulated Drug interference Antibody interference

Adapted from [7]

Table 2. Types and description of most common prep-analytical errors

Pre-analytical errors	Description
Hemolyzed samples	Presence of pink to red tinge in serum or plasma
Insufficient sample	Serum obtained not enough for requested test
Incorrect sample tube	Most samples received should not be in anticoagulated tubes
Sample not on ice	Samples for arterial blood gases analysis not transported on ice
Incorrect sample identification	Mismatch between name on sample and request form
Tube broken in centrifuge	The use of different tube sizes for sample collection
Delay in sample transportation	Samples were not sent to the laboratory on time
Expired reagents	Some reagents expired before use
Sample mix up	Samples intended for other laboratories were sent to the biochemistry lab

Adapted from [35]

2. SUMMARY

The pre-analytical phase of the total testing process is most prone to errors. The number of errors depend on the management of samples. The clinical laboratory must pay more attention to the good handling of samples. Preanalytical quality indicators include the appropriateness of test selection, patient/samples identification, samples collected in inappropriate containers or with insufficient volumes, hemolyzed or clotted samples, improperly stored samples or samples damaged in transport. Preanalytical error prevention demands, good communication and cooperation among all health professionals. The continuous education of personnel involved in procedures for the collecting handling preparing and transporting specimens is critically important for proper understanding of the effects of preanalytical variables on specimen quality and the reliability of test results. Studies have shown that "pre"-preanalytical errors predominated in the laboratory ranging from (46 – 68%), while the conventional pre-analytical account for (3-5%) [5].

3. CONCLUSION

Preanalytical phase of total testing processes are generally held outside the clinical laboratory which are mostly not under the total control of laboratory management. The implementation of ISO 15189:2012 quality management guidelines in the preanalytical phase should be adopted in order to prevent or reduce errors to an acceptable limit because the errors in this initial phase of the laboratory testing are preventable since human factors involved are well understood and defined. Therefore, inter departmental communication and cooperation of all stakeholders are crucial for effective monitoring and quality control for continuous quality improvement. It is therefore recommended that active monitoring and control systems of the errors that occurred in the non-laboratory settings should be monitored and sustained to ensure reliable testing.

COMPETING INTERESTS

Author has declared that no competing interests exist.

REFERENCES

1. Plebani M, Sciacovell L, Aita A, Pelloso M, Chiozza ML. Performance criteria and quality indicators for the pre-analytical phase. Clinical Chemistry and Laboratory Medicine (CCLM). 2015;53(6):943-948.
2. Englezopouloa A, Kechagia M, Chatzikinukou R, Kancllopoalon M, Valenti M, Masedu F. Pre-analytical errors as quality indicators in clinical laboratory. Austin J. Public Health Epidemol. 2016; 3(5):1048-1056.
3. Wagar EA, Yan S. the laboratory and patient safety clinical laboratory medicine. 2007;27:909-930.
4. Agarwal R, Chaturvedi S, Chhillar N, Goyal R, Part 1 Triputtri CB. Role of intervention on Laboratory performance; Evaluation of Quality Indicators in a Tertiary Care Hospital. Indian Journal of Clinical Biochemistry. 2012;27:61-68.
5. Harkins R. Managing the pre- and post-analytical phases of the total testing process. Ann Laboratory Medicine. 2012; 32:5-16.
6. Hammerling JA. A review of medical errors in laboratory diagnostics and where we are today laboratory medicine. 2012;43(2): 41-44.

7. Pal Bela S, Lars O. Error tracking in clinical biochemistry laboratory. Clin Chem Lab Med. 2009;47(10):1253-1257.
8. ISO 15189. Medical Laboratories—particular requirements for quality and competence. ISO, Genera; 2012.
9. Lippi G, McBride KB, Belulora D, Bowen R, Church S, Delanghe J. Pre-analytical quality improvement: In quality, we trust. Clinical Chem Laboratory Medicine. 2013; 51:229-241.
10. Marin AG, Ruiz FR, Hidalgo MP, Mandoza PM. Pre-analytical errors management in the clinical laboratory: A five-year study. Biochemia Medica. 2014;24:248-257.
11. Grasas A, Ramalhinho H, Pessoa LS, Resende MGC, Caballe L, Barba N. On the improvement of blood sample collection at clinical laboratories. BMC Health Services Research. 2014;14:12.
12. Stankovic AK, Delauri E. Quality improvements in the pre-analytical phase: Focus on Urine Specmen work flow MLO Med Lab Obs. 2008;28:339-350.
13. Ambruster DA, Overdash DR, Reyes J. Clinical chemistry laboratory automation in the 21st Century-Amat Victorla Curam (Victory loves careful preparation) Clinical Biochem Rev. 2014;35:143-153.
14. Saurav P, Brijesh M, Ashok KD. Pre-Analytical Errors in the clinical laboratory and how to minimize them. International Journal of Bioassays. 2013;2:551-553.
15. Plebani M, Laposata M Lundberg GD. The Brain –to – Brain loop concept for laboratory Testing 40 years after its introduction. Ann J Clini Pathol. 2011;136: 829-833.
16. Lippi G, Chance JJ, Church S, Dazzi P, Fontana R, Giavanna D. Pre-analytical quality improvement; from dream to reality. Clin Chem Lab Med. 2011;49:1113-1126.
17. Plebani M. Laboratory errors. How to improve pre – and post –analytical phase? Biochemia Medica. 2007;17:5-9.
18. Green SF. The cost of poor blood specimen quality and errors in pre-analytical processes. Clin Biochem. 2013; 46:1175-1179.
19. Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem. 2010;47:101-110.
20. Lippi G, Guidi GC. Risk management in the pre-analytical phase of laboratory testing. Clin Chem Lab Med. 2007;45:720-727.
21. Westgard JO. Basic QC practices 3rd Ed. Training in statistical Quality control for medical laboraories. 2010;309-325.
22. Plebani M. Errors in clinical laboratories or errors in laboratory medicine? Clin Chem Lab Med. 2006;44:750-759.
23. Tarkan S, Paisant C, Shneiderman B, Hettinzer AZ. Reducing missed laboratory results: Defining temporal responsibility, generating user interface for test process tracking and retrospective analyses to identify problems. AMIA Annu Symp Proce. 2011;1382-1391.
24. Pennsylvania Patient Safety Advisory, Reducing Errors in Blood specimen labelling; a multi hospital intiative pa patient Saf Advis. 2011;8:47-52.
25. Makitalo O, Likamen E. Improving quality at the pre-analytical phase of Blood sampling, Literature review. International Journal of Biomedical Laboratory Sciences (IJBLS). 2013;1:7-16.
26. Fedeli LG, Vidigal PG, Leite CM, Castillos CD, Pinentel RA, Maniero VC. Logistics of collection and transportation of biological samples and the organization of the central laboratory in the ELSA –Brazil. Rev Saude Publica. 2013;47:63-71.
27. Dikmen ZG, Pinar A, Akbiyi F. Specimen rejection in laboratory medicine. Necessary for Patient Safety? 2015;25:377-385.
28. Lippi G, Blanknert N, Bonini P, Green G, Kitchen S, Palicka V. Hemolysis an overview of the leading case of unsuitable specimens in clinical laboratories. Clin Chem Lab Med. 2008;46:764-772.
29. CLSI HSI –AZ. A quality management system model for health care. Clinical and Laboratory Standards Institute, Wayne, PA; 2004.
30. CLSI GP 26 – A3. Application of a quality management system model for laboratory services. Clinical and Laboratory Standards institute, Wayne PA; 2004.
31. US Centres for Medicare and Medicaid services (CMS). Medicare, Medicaid, and CLIA Programs. Laboratory Requirements Relating to quality systems and certain personnel Qualifications. Final Rule Fed. Regist. 2003;16:3640–3714.
32. Howerton D. Beyond CLIA regulation, quality management system international guidelines and standards. Division of Laboratory Systems CDC Presented at CLIAC Meeting; Sept 6, 2007. Available:wwwn.cdc.gov/cliac/pdf/Addenda/cliac 0907/Addendum PI, pdf

33. Lippi G, Bassi A, Brocco G, Montagnana M, Salvagno GL, Guidi GC. Preanalytical error tracking in a laboratory medicine department: Results of a 1 year experience. Clinchem. 2006;52:1442-1443.
34. Howanitz PJ. Errors in laboratory medicine: Practical lessons to improve patient safety. Arch Pathol Lab Med. 2005; 129:1252-1261.
35. Najut D. Prevalence of preanalytical errors in clinical chemistry diagnostic labs in Suleiman City of Iraq. Kurdistan. PLOS ONE. 2017;12(1):e0170211. DOI: 10 1371/journalpone0170211
36. Lippi G, Banfi G, Buttarello M, Ceriolti F, Daves M, Dolci A, et al. Recommendations for detection and management of unsuitable samples in clinical laboratories. Clin Chem Lab Med. 2007;45:728-736.

Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sciencedomain.org/review-history/26691